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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,300	11/12/2003	Hosheng Tu	GLAUKO.1C3CP1	5751

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/21/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/706,300	TU ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. In response to the restriction requirement imposed by the Examiner in the Office action mailed 12 June 2006, applicant has elected claims 1-18, canceling claims 19-45. Accordingly, claims 1-18 are currently pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4, 5, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,450,984 to Lynch et al.

In the specification and figures, Lynch discloses the apparatus as claimed by applicant. With regard to claims 1, 2, 4, and 5, Lynch discloses an implant 100 with a body compised of a biocompatible material that may comprise a drug or therapeutic agent deliverable to adjacent tissues (which indicates the agent is located on the outside of the implant, meeting applicant's limitation drawn to a coating) wherein the implant comprises an outlet end or distal portion sized and shaped to reside in Schlemm's canal, and an inlet end or proximal portion sized and shaped to reside in the

anterior chamber of the eye, wherein the device permits fluid communication from the anterior chamber to Schlemm's canal (see column 6, lines 50-64, column 9, lines 49-67).

With regard to claim 15, Lynch discloses that the device may be made of various polymers (see column 9, lines 60-67).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3, 6, 7, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch et al in view of US 7,033,603 to Nelson.

In the specification and figures, Lynch discloses the device substantially as claimed by applicant with the exception of the particular drugs or materials used as bioactive agents in the device. Nelson discloses an implantable hydrogel device that provides drug delivery to various internal locations within a patient. The device disclosed by Nelson may include a growth factor, a gene, TGF-beta, and heparin (see column 7, lines 60-67, column 8, lines 1-22, column 18, lines 50-67, column 17, lines 36-41). It has been held to be within the general skill of a worker in the art to select a known material (or, in this case, drug or bioactive agent) on the basis for its suitability for the intended purpose (in this case, to provide therapeutic treatment) as a matter of

obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant disclosed by Lynch with the therapeutic agents disclosed by Nelson in order to provide the desired therapeutic treatment to the patient.

6. Claims 9, 10, 12-14, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,984 to Lynch in view of US US 2005/0119737 to Bene et al.

In the specification and figures, Lynch discloses the device substantially as claimed by applicant with the exception of the location and type of therapeutic agent located on the implant. With regard to claims 9, 10, 12, 13, and 18, Bene discloses an ocular implant with a body 106 that may comprise a drug or bioactive agent impregnated within or as a coating on the housing (see FIG 2, paragraphs 0033, 0046, 0059). Bene discloses that the drug associated with the implant may include a glaucoma treatment (which necessarily lowers the intraocular pressure of the eye, since treatment of glaucoma involves the lowering of intraocular pressure), anti-inflammatory, or anticancer (antiproliferative) agent loaded onto the exterior surface of the device, including the head and foot, wherein the agent may be a polymer layer (which examiner is interpreting as equivalent to the claimed film) containing the bioactive agent (see paragraph 0059, claim 97). The implant and drug layers are constructed to provide drug transmissions to various portions of the eye over a prolonged period of time (see paragraph 0063).

It has been held to be within the general skill of a worker in the art to select a known material (or, in this case, drug or bioactive agent) on the basis for its suitability for the intended purpose (in this case, to provide therapeutic treatment) as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the implant disclosed by Lynch with the therapeutic agents disclosed by Bene in order to provide the desired therapeutic treatment to the patient.

With regard to claim 14, Bene discloses that the shunt body may be constructed of hydrogels (which are biodegradable, see paragraph 0045). It has been held to be within the general skill of a worker in the art to select a known material on the basis for its suitability for the intended purpose as a matter of obvious design choice. See MPEP 2144.07. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant disclosed by Lynch with the materials disclosed by Bene in order to provide the desired therapeutic treatment to the patient

With regard to claims 16-17, Bene discloses that an anti-infective agent may be disposed on a filter 262, which may be located at the outlet end of the device (see FIG 22, paragraphs 0066, 0077). The filter may comprise a pillar structure (see FIGS 38-42), and serves to prevent bacterial infection. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a therapeutic agent at the outlet of the implant disclosed by Lynch in order to prevent bacterial infection, as taught by Bene.

Response to Arguments

7. Applicant's amendment and arguments filed 12 December 2006 have been entered and considered.

8. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
8 February 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER